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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/893,346	06/28/2001	Wayne D. Comper	48643-015	2638

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600 13th Street, N.W.  
Washington, DC 20005-3096

EXAMINER

BROWN, STACY S

ART UNIT	PAPER NUMBER
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1648

10

DATE MAILED: 05/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/893,346

Applicant(s)

COMPER, WAYNE D.

Examiner

Stacy S Brown

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 23 April 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-5,7-14,16-18 and 20-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5,7-14,16-18 and 20-24 is/are rejected.
- 7) ☒ Claim(s) 21 and 24 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 09/415,217.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. Applicant's amendment filed April 23, 2003 is acknowledged and entered. Upon further review and consideration, the following new rejections are set forth below. Claims 1-5, 7-14, 16-18 and 20-24 are pending and examined.

#### ***Claim Objections***

2. Claim 21 is objected to for a minor informality: the phrase "wherein decreasing amount of the intact modified form" should have "a" inserted before "decreasing".

Claim 24 is objected to for a minor informality: the phrase "present in the sample in increasing amount over time" should have "an" inserted before "increasing".

#### ***Claim Rejections - 35 USC § 112***

3. Claims 1-5, 7-14, 16-18 and 20-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Claims 1 and 20 are unclear because the methods involve detection of both native and intact modified protein, however, the presence of native or intact modified protein is used to correlate effectiveness of the treatment agent. It is unclear why both forms are detected, yet only one is used in the correlation step.
- Claim 1, which form of the protein is being referred to in the phrase "decreasing amount of the protein over time in the urine"?

Art Unit: 1648

- Claim 1, “intact modified” is unclear. The specification defines intact/modified protein to be detectable by HPLC (page 10, paragraph 52). Intact protein, modified protein and a modified form of a protein are undetectable by conventional radioimmunoassay (page 10, paragraph 52). How is intact modified protein different from fragmented protein? The specification defines “fragmented albumin” to be that is not detect by conventional anti-albumin antibody (page 10, paragraph 52). How would one detect intact modified forms of globulin, insulin, lipoprotein?
- Claim 2 is unclear because the list of renal diseases and renal complications of diseases is not consistent with the meaning of renal diseases or renal complications. For example, trauma, surgery, injury, burns, induction of anesthesia, drugs and drug abuse are not diseases or renal complications of disease.
- Claim 10 is unclear because “an antibody” is specific for both the native and intact modified forms of albumin. Either the antibody is specific for native albumin, or it is specific for intact modified albumin, but not both. Clarification is requested.
- Claim 12, which form of “the albumin” is being detected by the antibody?
- Claim 13 is missing a phrase after “comprises the steps of;”.
- Claim 21, there is no antecedent basis because claim 19 is canceled.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 8, 10, 18, 20 and 23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims are drawn to a method of assessing therapeutic effectiveness of a treatment agent by assaying for two forms of a protein: native and intact modified. The specification does not enable one of skill in the art to detect the intact modified form of a protein with an antibody or dyes.

The instant specification defines intact/modified protein to be detectable by HPLC (page 10, paragraph 52). Intact protein, modified protein and a modified form of a protein are undetectable by conventional radioimmunoassay (page 10, paragraph 52). This definition of modified protein is inconsistent with the definition found in the parent application USSN 09/415,217, the prosecution history of which shows that intact modified albumin is detected by non-antibody means only. Clarification is requested regarding the definition of "intact/modified protein", intact protein, modified protein, and intact modified protein. Applicant is requested to use "intact modified" consistently, not to be confused with intact/modified which implies intact protein and modified protein. Concerning dyes that detect intact modified protein, the specification is only enabling for detecting modified forms of protein, not intact modified protein (page 15, paragraph 82).

Given the teachings of the specification and the parent application's prosecution history and claims, the instant claims are not enabling for detecting intact modified protein with antibodies or dyes.

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5. Claims 1-5, 7, 13, 14, 16, 17, 20, 21 and 23 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for assessing therapeutic effectiveness of an agent by detecting intact modified albumin, does not reasonably provide enablement for detecting any intact modified protein. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims. The nature of the invention is drawn to the detection of intact modified albumin found in the urine which indicates early stage renal disease or renal complications. The breadth of the claims is drawn to the detection of virtually any intact modified protein found in the urine and correlating the protein with a disease that leads to renal disease or renal complications. The prior art does not teach the detection of intact modified albumin (as defined by its ability to be detected only by non-antibody means), or any other such intact modified protein. The prior art of record teaches the detection of fragments to detect disease. One of skill in the art would not know which protein corresponds to which disease when detecting intact modified protein. The only working examples shown by Applicant are those detecting intact modified albumin (examples in the specification). While the proteins listed in claim 7 can be present in the urine, the specification does not enable one to know how those particular proteins are linked with renal disease or renal complications. For example, a person with hypertension is tested according to Applicant's method for renal disease. One of skill would not know which protein to assay for, much less the intact modified form of the protein. Given the lack of guidance in the specification, the breadth of the claims, the state of the art and the lack of working examples, the claims are only enabled for the detection of renal disease by assaying for intact modified albumin by non-antibody means.

*Conclusion*

6. No claim is allowed. This Office Action is non-final because new grounds of rejection were made. Some new rejections were in response to Applicant's amendment, however, rejections were made that could have been made earlier in prosecution.

Papers relating to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 located in Crystal Mall 1. The Fax number for Art Unit 1648 is (703) 308-4426. All Group 1600 Fax machines will be available to receive transmissions 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Stacy S. Brown, whose telephone number is (703) 308-2361. The Examiner can normally be reached on Monday through Friday from 6:30 AM-4:00 PM, (EST). If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, James C. Housel, can be reached at (703) 308-4027. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

*SSB*

Stacy S. Brown  
May 9, 2003

*James C. Housel*  
JAMES HOUSEL 5/17/03  
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